

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division
DP Barcode D261691 Reg. No. or File Symbol: 9480-T
Manufacturing-Use [] or End-Use Product [X] Case #

TO: Tony Kish
PM Team No. 33

FROM: Anna Skapars, Chemist
Chemistry-Toxicology Team (CTT)
Product Science Branch (PSB)

THRU: Karen Hicks, Team Leader
Chemistry/Toxicology Team (CTT)
Product Science Branch (PSB)

Karen Hicks
3/8/00

THRU: Michele E. Wingfield, Branch Chief
Product Science Branch (PSB)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

BACKGROUND:

This application is for the registration of a new product, ^ano rinse hard surface sanitizing wipe for use on food contact surfaces.

FINDINGS:

The Confidential Statement of Formula dated 2/29/00 does not agree with the proposed label and the CSF is not acceptable.

According to the Confidential Statement of Formula dated 2/29/00, the label claim should be:

Active Ingredients

| | |
|---|-----------|
| Alkyl (C12 67%, C14 25%, C16 7%, C8, C10, C18 1%) | |
| Dimethyl benzyl ammonium chloride | 0.04745% |
| Isopropyl | 5.48000% |
| Inert Ingredients | 94.47255% |

Submit a revised correct Confidential Statement of Formula and a revised label. The ingredient statement in the label must agree with the Confidential Statement of Formula.

Delete from the label claims "Inert Ingredients do not include the towelette" and "Industrial Strength".

This formulation is cleared by the Federal Food, Drug and Cosmetic Act for use on food contact surface terminal sanitizing rinse.

Provided product chemistry data for Guideline Series 61, 62 and 63 in MRID No. 449774-13, 449774-14 and 449774-15, ~~these data~~ are in compliance with 40 CFR, Part 158.155 through 158.190 and they satisfy the product chemistry data for this product.

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division
DP Barcode D261691 Reg. No. or File Symbol 9480-T
Manufacturing-Use [] or End-Use Product [☒] Case# _____

TO: Tony Kish
PM Team No. 33

FROM: Anna Skapars, Chemist Anna Skapars. 03-08-2000
Chemistry-Toxicology Team (CTT)
Efficacy and Science Support Branch (ESSB)

THRU: Karen P. Hicks, CT Team Leader
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

THRU: Michele E. Wingfield, Branch Chief
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

*This application is for registration of new product no
rinse hard surface sanitizing wipe for use on food
contact surfaces.*

Findings:

*Confidential Statement of Formula dated 02-29-2000
does not agree with the proposed label and CSF
is not acceptable.*

*According to Confidential Statement of Formula
dated 02-29-2000 the label claim should be:*

Active Ingredients

Alkyl (C₁₂ 67%, C₁₄ 25%, C₁₆ 7%, C₈, C₁₀, C₁₈ 1%)

dimethyl benzyl ammonium chloride - - - - - 0.04745 %

Isopropyl Alcohol - - - - - 5.48000 %

Inert Ingredients - - - - - 94.47255 %

*Submit revised correct Confidential Statement of Formula
and revised label. The ingredient statement in the
label must agree with Confidential Statement of Formula.*

*Delete from the label claims "Inert Ingredients do
not include the towelette" and "Industrial strength".*

see page 2

2.

This formulation is cleared by the Federal Food, Drug and Cosmetic Act for use on food contact surface terminal sanitizing rinse.

Provided product chemistry data for Guideline Series 61, 62 and 63 in MRID No. 449774-13, 449774-14 and 449774-15, these data are in compliance with 40 CFR part 158.155 through 158.190 and they satisfy product chemistry data for this product.

STUDY TITLE

PRODUCT CHEMISTRY DATA

449774-15

DATA REQUIREMENTS

GUIDELINE SERIES 63

AUTHOR

ANN P. YOUNG

STUDY COMPLETED ON

OCTOBER 20, 1999

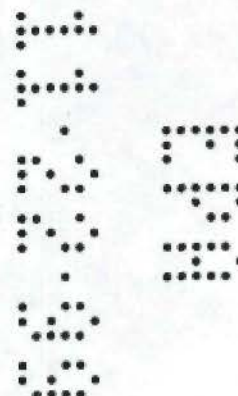
PERFORMING LABORATORY

PDI
TWO NICE-PAK PARK
ORANGEBURG, NY 10962

LABORATORY PROJECT ID

6609-NS-I-66-B-1

PAGE 1 OF 10



STATEMENT OF DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 10(d)(1)(A), (B) or (C).

COMPANY PDI. HEALTHCARE DIVISION OF NICE PAK PRODUCTS

COMPANY AGENT ANN P. YOUNG
TYPED NAME

Ann Young / RY
SIGNATURE

MANAGER REGULATORY AFFAIRS
TITLE

OCTOBER 20, 1999
DATE

10/20/99

GLP STATEMENT

This study does not meet the requirements for 40 CFR Part 160 and differs in the following ways:

1. 40 CFR 160 DOES NOT APPLY TO THE INFORMATION CONTAINED IN THIS PARTICULAR STUDY AS PER 40 CFR 160.135
2. INFORMATION WAS OBTAINED FROM MATERIAL SAFETY DATA SHEETS AND INTERNAL TECHNICAL BULLETINS
3. HOWEVER, SOME OF THE INFORMATION CONTAINED IN THIS STUDY WERE OBTAINED UNDER GENERALLY RECOGNIZED ACCEPTABLE LABORATORY PROCEDURES AND THEIR RESULTS ACCURATELY REFLECTS THE RAW DATA OBTAINED.

SUBMITTER:

PDI, HEALTHCARE DIVISION OF NICE PAK PRODUCTS Ann Young VG 10/20/99
typed name signature date

SPONSOR:

PDI, HEALTHCARE DIVISION OF NICE PAK PRODUCTS Ann Young VG 10/20/99
typed name signature date

STUDY DIRECTOR ANN P. YOUNG Ann Young VG 10/20/99
typed name signature date

PRODUCT CHEMISTRY DATA REQUIREMENTS

III. PHYSICAL AND CHEMICAL CHARACTERISTICS - SERIES 63

| | |
|--|--|
| 63-2 - Color | White wipe with colorless liquid Method: Visual observation |
| 63-3 - Physical State | Liquid solution with solid wipe Method: Visual observation |
| 63-4 - Odor | Slight alcohol Method: Olfactory determination |
| 63-5 - Melting point | Formulators Exemption: Only required for TGAI |
| 63-6 - Boiling point | Formulators Exemption: Only required for TGAI |
| 63-7 - Specific Gravity | 0.985-0.995 @ 25 degree C Method: Refer to Attachment A for specific method |
| 63-8 - Solubility | Formulators Exemption: Only required for TGAI |
| 63-9 - Vapor Pressure | Formulators Exemption: Only required for TGAI |
| 63-10 -Dissociation Constant | Formulators Exemption: Only required for TGAI |
| 63-11 -Octanol/water partition Coefficient | Formulators Exemption: Only required for TGAI |
| 63-12 -pH | 10.0 - 10.5 Method: Refer to Attachment A for specific method |
| 63-13 -Stability | Formulators Exemption: Only required for TGAI |
| 63-14 -Oxidizing/Reducing Action | Product doesn't contain oxidizing/reducing agents. |
| 63-15 -Flammability | Not Flammable: contains no flammable ingredients |

| | |
|-------------------------------------|--|
| 63-16 -Explosability | Contains no explosive ingredients |
| 63-17 -Storage stability | Stable: 30 day accelerated study : Refer to end of this data package for detailed report chart (Attachment B). The expressed liquid calculations are in Attachment C. |
| 63-18 -Viscosity | Not applicable since product is a wipe |
| 63-19 -Miscibility | Not an emulsifiable liquid, all ingredients are water soluble. |
| 63-20 -Corrosion Characteristics | Non corrosive to plastic canisters (polyethylene). Refer to the end of this data package for detailed report chart (Attachment D). |
| 63-21 -Dielectric Breakdown Voltage | Product is not used around electrical equipment |

ADDENDUM:

A. Conditions: the sample testing was done at room temperature.

Sources of data:

- The above information was obtained from Material safety data sheets and internal preliminary testing lab notes.